

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESale PRICE)	
LITIGATION)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	
<i>the Florida Keys, Inc., v. Abbott Laboratories,</i>)	
<i>Inc.,</i>)	
CIVIL ACTION NO. 06-11337-PBS)	

UNITED STATES' MOTION TO MAINTAIN SEAL ON DOCUMENTS

As exhibits to its Objections to the August 13, 2007 Order by Magistrate Judge Bowler, the United States submitted two privileged documents to this Court, along with a motion requesting leave to file the documents under seal. On September 17, 2007, this Court entered an electronic order granting the United States' motion for leave to file the exhibits under seal, but noted, "However, I have reviewed the documents and they are not self-explanatory. The government will have to explain why the privilege applies."

In response to the Court's ruling, the United States respectfully submits, in open court, the following explanation of the deliberative process privilege that attaches to the two documents.

Exhibit 2 to the United States' Objections, which bears the bates numbers HHD 903-0520-0523, is a draft of revisions to a carrier manual regarding Medicare coverage of durable medical equipment. The typed draft contains numerous handwritten alterations and suggestions for changes in the final version. The draft document does not reflect a final agency statement on

any aspect of DME coverage, but rather reflects an internal, preliminary set of suggestions for establishing agency policy concerning DME coverage.

The deliberative process privilege protects evidence from disclosure if it is both pre-decisional and deliberative in nature, containing opinions, recommendations, or advice about agency decisions. *See Renegotiation Bd. v. Grumman Aircraft Eng'g Corp.*, 421 U.S. 168, 184 (1975). Exhibit 2 is predecisional, in that it temporally preceded an agency decision on DME coverage policy, and, as a draft, was created with the aim of assisting the agency in reaching a final decision on the issue. *See Providence Journal Co. v. Dep't of Army*, 981 F.2d 552, 557 (1st Cir. 1992) (setting forth test for finding documents predecisional).¹ The document is also deliberative, in that (as a draft) it reflects the internal back-and-forth within the agency concerning an agency decision, in this case the establishment and articulation of agency policy concerning DME Coverage. *See id.* at 560 (“the appropriate judicial inquiry is whether the agency document was prepared to facilitate and inform a final agency decision or deliberative function entrusted to the agency.”). Therefore, the document meets all of the substantive requirements to be covered under the deliberative process privilege. This Court has noted in the past that draft documents, such as Exhibit 2, “have frequently been held to be deliberative

¹*Providence Journal* held that a document will be considered “predecisional” if it: (1) relates to a specific agency decision, (2) precedes that decision temporally, and (3) was prepared with the purpose of assisting a final agency decision on the issue. *See Providence Journal*, 981 F.2d at 557. It is important to note that the test set forth in *Providence Journal* is not intended to be an exclusive method of determining whether a document can be considered predecisional. The Supreme Court has recognized that, while predecisional documents will generally be created prior to the agency decisions to which they contributed, agency decision making is a continuous and ongoing process, and documents containing protected recommendations or advice may not ripen into a specific agency decision – and indeed, may be subsequent to related agency decisions. *See NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 151 (1975), (“[a]gencies are, and properly should be, engaged in a continuing process of examining their policies; this process will generate memoranda containing recommendations which do not ripen into agency decisions, and the lower courts should be wary of interfering in this process.”).

material” *AFL-CIO v. United States Dept. Of Health and Human Servs.*, 63 F. Supp. 2d 104, 108.

Exhibit 3 to the United States’ objections, bearing the bates numbers HHC-906-0001-0002, is a “Discussion Memo” from early 2002 concerning CMS’s response to certain carrier investigations of particular billings for Lupron. The document sets forth background on the issue, lays out options for responding, and lists other considerations relevant to addressing the issue discussed in the memorandum. The memorandum is stamped “CONFIDENTIAL,” and contains handwritten marginalia reflecting the author’s comments on several aspects of the memorandum.

This document is predecisional, as it precedes a final agency decision as to how to respond to the matter discussed in the memorandum, and it was clearly prepared to assist the agency decisionmakers in coming to a decision on that issue. Furthermore, it is deliberative, as it sets forth options and considerations for how the agency should address the issue, and is clearly part of the agency’s internal, consultative policymaking process. *See, e.g., Grand Cent. P’ship, Inc. v. Cuomo*, 166 F.3d 473, 482 (2d Cir. 1999) (privilege protects “recommendations, draft documents, *proposals*, *suggestions*, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency.”) (emphasis added). The document is therefore privileged under the standards governing the deliberative process privilege.

For the foregoing reasons, the United States respectfully requests that this Court maintain the seal on these documents.

Respectfully submitted,

For the United States of America,

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Dated: September 20, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above “**UNITED STATES’ MOTION TO MAINTAIN SEAL ON DOCUMENTS**” to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: September 20, 2007

/s/ John K. Neal
John K. Neal